Long-term Follow-up Study for Participants Previously Treated with Ciltacabtagene Autoleucel

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase IV	300
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	Terapia génica

Información

Identificador
2023-505530-10-00 (CTIS)

Cod. Protocolo
68284528MMY4002

Transicionado 2020-005521-84

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Multiple Myeloma

Título Científico
Long-term Follow-up Study for Participants Previously Treated with Ciltacabtagene Autoleucel

Justificación

No aportado

Objetivo Principal

To collect long-term follow-up data on delayed adverse events after administration of cilta-cel, and to characterize and understand the long-term safety profile of cilta-cel.

Variables de Evaluación Primaria

Number of subjects with delayed adverse events associated with administration of Cilta-cel. The following adverse events will be collected: - New malignancies and recurrence of preexisting malignancy (all grades)
- New incidence or exacerbation of a preexisting neurologic disorder (all grades)
- New incidence or exacerbation of a preexisting rheumatologic or other autoimmune disorder (all grades)
- New incidence of Grade 3 hematologic disorder including hypogammaglobulinemia (Years 1-5).Serious hematologic disorder including hypogammaglobulinemia (Years 6-15).
- New incidence of Grade 3 infection (Years 1-5).Serious infection(Years 6-15).
- All SAEs (Years 1-5). Only related SAEs as assessed by the Investigator (Years 6-15).

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To collect additional long-term data on replication competent lentivirus (RCL), cilta-cel persistence, efficacy, and overall survival

Variables de Evaluación Secundaria

- Number of subjects with measurable RCL in peripheral blood. - Number of subjects with CAR transgene level >lower limit of quantitation (LLOQ) in peripheral blood cells. - Assessment of the pattern of lentiviral vector integration sites if at least 1% of cells in the blood sample or new malignancy are positive for vector sequences. - Long term follow-up on CAR-T therapy efficacy if the subject does not have confirmed disease progression or does not initiate subsequent antimyeloma therapy at the entry of the study and at any time of during the study. - Overall Survival (OS)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

All subjects who received cilta-cel in a Company-sponsored clinical study are candidates for Study MMY4002. The inclusion criteria for the study are described below: 1. Subjects who have received at least one dose of cilta-cel in a Company-sponsored clinical study.
2. Subjects who have provided informed consent for Study MMY4002.

Criterios de Exclusión

No exclusion criteria are applicable in this study.

Calendario

(Última actualización: 26/11/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
17/05/2022	No aportado	02/11/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Centros

Activo (18/04/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Hematología

Activo (24/10/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Hematología

Medicamentos

CARVYKTI 3.2 × 10^6 1.0 × 10^8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01XL05 - CILTACABTAGEN AUTOLEUCEL
Principios Activos: N/A

Huérfano Experimental

Sin resultados

Long-term Follow-up Study for Participants Previously Treated with Ciltacabtagene Autoleucel

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase IV	300
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	Gene therapy

Information

Identifier
2023-505530-10-00 (CTIS)

Protocol Code
68284528MMY4002

Transitioned 2020-005521-84

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Multiple Myeloma

Scientific Title
Long-term Follow-up Study for Participants Previously Treated with Ciltacabtagene Autoleucel

Rationale

Not provided

Main Objective

To collect long-term follow-up data on delayed adverse events after administration of cilta-cel, and to characterize and understand the long-term safety profile of cilta-cel.

Primary Endpoints

Number of subjects with delayed adverse events associated with administration of Cilta-cel. The following adverse events will be collected: - New malignancies and recurrence of preexisting malignancy (all grades)
- New incidence or exacerbation of a preexisting neurologic disorder (all grades)
- New incidence or exacerbation of a preexisting rheumatologic or other autoimmune disorder (all grades)
- New incidence of Grade 3 hematologic disorder including hypogammaglobulinemia (Years 1-5).Serious hematologic disorder including hypogammaglobulinemia (Years 6-15).
- New incidence of Grade 3 infection (Years 1-5).Serious infection(Years 6-15).
- All SAEs (Years 1-5). Only related SAEs as assessed by the Investigator (Years 6-15).

Temporary moments of secondary assessment

Not provided

Secondary Objective

To collect additional long-term data on replication competent lentivirus (RCL), cilta-cel persistence, efficacy, and overall survival

Secondary Endpoints

- Number of subjects with measurable RCL in peripheral blood. - Number of subjects with CAR transgene level >lower limit of quantitation (LLOQ) in peripheral blood cells. - Assessment of the pattern of lentiviral vector integration sites if at least 1% of cells in the blood sample or new malignancy are positive for vector sequences. - Long term follow-up on CAR-T therapy efficacy if the subject does not have confirmed disease progression or does not initiate subsequent antimyeloma therapy at the entry of the study and at any time of during the study. - Overall Survival (OS)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

All subjects who received cilta-cel in a Company-sponsored clinical study are candidates for Study MMY4002. The inclusion criteria for the study are described below: 1. Subjects who have received at least one dose of cilta-cel in a Company-sponsored clinical study.
2. Subjects who have provided informed consent for Study MMY4002.

Exclusion criteria

No exclusion criteria are applicable in this study.

Calendar

(Last Update: 26/11/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
17/05/2022	Not aported	02/11/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (18/04/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Hematología

Active (24/10/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Hematología

Medication

CARVYKTI 3.2 × 10^6 1.0 × 10^8 cells dispersion for infusion

DISPERSION FOR INFUSION

INTRAVENOUS USE

ATC code: L01XL05 - CILTACABTAGEN AUTOLEUCEL

Active Principles: N/A

Orphan **Experimental**

No results